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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/499,526	02/10/2000	Kuanghui Lu	CIBT-P01-058	1398

28120 7590 12/17/2002

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EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 12/17/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/499,526

Applicant(s)

LU ET AL.

Examiner

Regina M. DeBerry

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-33, 35-63, 65-67, 69-71 and 73-91 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 15-23, 28-33, 39, 45, 46, 50, 51, 53, 54, 57-60, 63, 76-78, 85 and 87-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-13, 15-33, 35-63, 65-67, 69-71 and 73-91 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1-12, 24-27, 35-38, 40-44, 47-49, 52, 55, 56, 61, 62, 65-67, 69-71, 73-75, 79-84 and 86.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03 October 2002 (Paper No. 29) has been entered.

Status of Application, Amendments and/or Claims

Claims 14, 34, 64, 68, 72 were cancelled. Claims 1-12, 24-27, 35-38, 40-44, 47-49, 52, 55, 56, 61, 62, 65-67, 69-71, 73-75, 79-84 and 86 are withdrawn from consideration. Claims 13, 15-23, 28-33, 39, 45, 46, 50, 51, 53, 54, 57-60, 63, 76-78, 85 and 87-91 are under examination.

Claim Objections

Claims 30, 31, 39 are objected to because of the following informalities: The instant claims depend from a cancelled claim (claim 14) and require amendment to limit to elected invention. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 15-23, 28-33, 39, 45, 46, 50, 51, 53, 54, 57-60, 63, 76-78, 85 and 87-91 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

A method for altering the glucose-responsiveness of a pancreatic islet or cell comprising administering to the pancreatic islet or cell PYY thereby increasing the glucose-responsiveness of the pancreatic islet or cell

A method for altering glucose metabolism in an animal identified as having a disease associated with abnormal glucose metabolism, comprising administering to the animal an amount of PYY, wherein the amount is therapeutically effective to induce or enhance glucose responsiveness in the animal, thereby altering glucose metabolism in the animal

A method for treating a disease associated with altered glucose metabolism, comprising administering to an animal identified as having a disease associated with altered glucose metabolism an amount of a composition comprising PYY, wherein the amount is sufficient to increase the glucose responsiveness of a pancreatic islet or cell in the animal

A method for maintaining or restoring a function of pancreatic β cells, comprising administering to a pancreatic islet or cell a composition comprising PYY, thereby increasing glucose responsiveness of pancreatic β cells,

A method for maintaining or restoring normal pancreatic islet function, comprising administering to a cultured pancreatic islet or cell PYY thereby increasing glucose responsiveness of pancreatic islets.

does not reasonably provide enablement for:

administering a peptidyl PYY agonist or

administering a peptidyl PYY agonist together with dipeptidylpeptidase inhibitor, insulin, or GLP1 or

a method wherein administering peptidyl PYY agonist causes maturation of pancreatic islet or cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification is not enabled for maturation of pancreatic islets or cells upon administering peptidyl PYY agonist. The specification has not demonstrated maturation of pancreatic islets or cell in response to peptidyl PYY agonist or PYY. While the specification does demonstrate glucose responsiveness of cells in culture upon administering PYY, this alone does not prove maturation. Pancreatic islets or cells express markers indicative of maturation. The specification fails to show that various assays were employed to show morphological changes, expression of specific genes or surface markers that demonstrate maturation has taken place.

The specification is not enabled for administering a peptidyl PYY agonist together with dipeptidylpeptidase inhibitor, insulin, or GLP1. The specification does not teach increased glucose responsiveness upon administering peptidyl PYY agonist (or PYY) **and** dipeptidylpeptidase inhibitor, insulin or GLP-1.

Lastly, the specification is not enabled for peptidyl PYY agonist. Peptidyl PYY agonist encompasses any biological equivalent, derivative or variant of PYY. The specification does not teach how to make and use any variant of PYY polypeptide or PYY agonist and provides no assay to evaluate the function of any modified polypeptide. The specification discloses increase glucose responsiveness upon administering PYY. The disclosure, however does not disclose increase glucose responsiveness upon administering peptidyl PYY agonists. The disclosure provides no guidance as to which regions of the protein would be tolerant of modification and which would not, and it provides no working example of any variant sequence which would be within the claims. It is in no way predictable that randomly selected mutations, deletions, etc. in the disclosed sequence would afford a protein having activity comparable to the one disclosed.

Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions (see Wells, 1990, Biochemistry 29:8509-8517). It would require an indeterminate quantity of

fundamentally unpredictable investigational experimentation of the skilled artisan to determine whether any modified polypeptide could be used in the same manner as the native exemplar. Such experimentation would be undue for one skilled in this art.

Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 15-23, 28-33, 39, 45, 46, 50, 51, 53, 54, 57-60, 63, 76-78 and 85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite because the structural metes and bounds of the term "peptidyl PYY agonist" cannot be determined.


Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

RMD
December 13, 2002